

INTERNATIONAL COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C.20231
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 October 2000 (03.10.00)	
International application No. PCT/GB00/00428	Applicant's or agent's file reference N.75820B CMK
International filing date (day/month/year) 10 February 2000 (10.02.00)	Priority date (day/month/year) 10 February 1999 (10.02.99)
Applicant HYLANDS, Peter, John et al	

1. The designated Office is hereby notified of its election made:

 in the demand filed with the International Preliminary Examining Authority on:

08 September 2000 (08.09.00)

 in a notice effecting later election filed with the International Bureau on:2. The election was was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Olivia TEFY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 18 JUN 2001
WIPO
PCT

14

Applicant's or agent's file reference N.75820B CMK	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/00428	International filing date (day/month/year) 10/02/2000	Priority date (day/month/year) 10/02/1999	
International Patent Classification (IPC) or national classification and IPC G01N33/15			
Applicant OXFORD NATURAL PRODUCTS PLC et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 8 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 08/09/2000	Date of completion of this report 13.06.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Bosma, R Telephone No. +31 70 340 2789 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00428

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-31 as originally filed

Claims, No.:

1-15 as received on 06/03/2001 with letter of 05/03/2001

Drawings, sheets:

1/7-7/7 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - the language of publication of the international application (under Rule 48.3(b)).
 - the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.: 16

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00428

the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-8,10-14
	No: Claims 9,15
Inventive step (IS)	Yes: Claims 1-8
	No: Claims 9-15
Industrial applicability (IA)	Yes: Claims 1-15
	No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1) Reference is made to the following documents:

D1: WO 96 18911 A (CONSEIL INTERPROFESSIONNEL DU;
VERCAUTEREN JOSEPH (FR); FORVEILLE) 20 June 1996 (1996-06-20)

D2: COOKE R J: 'Gel electrophoresis for the identification of plant varieties' JOURNAL OF CHROMATOGRAPHY A,NL,ELSEVIER SCIENCE, vol. 698, no. 1, 28 April 1995 (1995-04-28), pages 281-299, XP004022963
ISSN: 0021-9673

2) Notwithstanding the clarity objections raised against Claim 1 in Section VIII below, the following observations are based on the claims read in the light of the description.

Without the objections VIII 1a) and 1b), Claim 1 would have been novel (Art 33(2)PCT) and inventive (Art 33(3) PCT) relative to the prior art disclosed in D1 and D2.

D1 can be considered to represent the closest prior art.

It discloses:

a) a process of providing a standard specification (see e.g. p.3, lines19-24, and p. 9, line 23-p.10, line 4, disclosing the establishment of a collection of reference samples) for a medicinal plant material (see e.g. p. 9, line 12 and Claim 10, mentioning medicinal plants),

the process comprising:

b) preparing (see e.g. ex. 1 and corresponding Figures 6 and 7 disclosing sample preparation and subsequent discrimination of different plants) a test

extract of a sample of said plant material which is known to possess the property desired for the standard, submitting the test solution or test extract to NMR spectroscopy and recording a spectrum (see e.g. Claim 1 and Fig 1),
c) submitting data obtained from the NMR spectrum to a multivariate analysis (e.g. p. 16, line 23-p.18, line 3) to generate one or more points on a score plot (see e.g. Fig. 6),
d) obtaining results from the multivariate analysis, and defining a standard specification for the said plant material on the basis of these results (acc. to Fig. 6 and 7, different species can be clearly separated).

The subject-matter of Claim 1 differs from the disclosure of D1, in that it has the additional feature of one or more biological profiling techniques, which provide a quantifiable measure of the biological effect of the plant and which include a proteomics analysis.

The problem to be solved by this additional feature, is the determination of the relationship between plant compounds and their biological effect .

None of the documents cited in the International Search Report discloses or suggests the determination of this relationship. Therefore, Claim 1 is novel (Art.33(2)PCT) and inventive (Art.33(3) PCT).

3) Similarly, dependent Claims 2-8, relating to specific embodiments of the process of Claim 1, would also have satisfied the requirements of Art. 33(2) and (3) PCT.

4) Notwithstanding the clarity objections raised against Claim 9 in Section VIII below, the following observations are based on the claims read in the light of the description.

The present application does not satisfy Rule 33(2)PCT, because the subject-matter of independent Claim 9 and that of Claim 15 is not novel.

D1 discloses:

a) a process of providing a standard specification (see e.g. p.3, lines 19-24, and p. 9, line 23-p.10, line 4, disclosing the establishment of a collection of reference samples) for a medicinal plant material (see e.g. p. 9, line 12 and Claim 10, mentioning medicinal plants),

the process comprising:

b) preparing (see e.g. ex. 1 and corresponding Figures 6 and 7 disclosing sample preparation and subsequent discrimination of different plants) a test extract of a sample of said plant material which is known to possess the property desired for the standard, submitting the test solution or test extract to NMR spectroscopy and recording a spectrum (see e.g. Claim 1 and Fig 1),

c) submitting data obtained from the NMR spectrum to a multivariate analysis (e.g. p. 16, line 23-p.18, line 3) to generate one or more points on a score plot (see e.g. Fig. 6),

d) defining a region of acceptability around said points as at least a standard specification for said plant material (acc. to Fig. 6 and 7, different species can be clearly separated; a region or sphere of acceptability is defined by the clusters in the figures).

The feature of reflecting the totality of compounds in the plant material which respond to the NMR technique being used, is implicitly present in all NMR spectroscopic techniques.

Thus, Claim 9 is not novel.

Likewise, D1 discloses:

a method of comparing samples with a standard corresponding to a specific species (see e.g. Claim 14). Normally the provenance of such a species is known.

Therefore Claim 15 in combination with Claim 9 is not novel.

6) Moreover, if the objection against the clarity of Claim 9 had been overcome, the present application would not have satisfied Rule 33(3) PCT,

because the subject-matter of Claims 10-14 does not involve an inventive step.

Claim 10:

Performing a multivariate analysis using an unsupervised methodology is standard in processes of the type disclosed in D1.

Claim 11:

A person skilled in the art would contemplate establishing a standard specification for a mixture of several plants, as long as the plants can be clearly discriminated in the determined spectra.

Claims 12 -14:

The additional features of Claim 12 to 14 appear to be standard in a process of the type disclosed in D1 or D2.

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in documents D1 and D2, is not mentioned in the description, nor are these documents identified therein.

Re Item VIII

Certain observations on the international application

1) The present application does not satisfy Article 6 PCT, because the subject-matter of independent Claim 1 is not sufficiently clear.

a) It is unclear how a quantifiable measure of the biological effect of the plant material can be obtained, without the introduction of target cells (as in the description of the present application, p. 13, lines 7-9; and in dependent Claim 6).

b) There is a contradiction between lines 3-5 and lines 15-16 of Claim 1. In particular, "a test extract" possessing "the or each property required for the standard", does not agree with "the totality of the compounds in the plant material".

2) Similarly, the present application does not satisfy Article 6 PCT, because the subject-matter of independent Claim 9 is not sufficiently clear.

There is a contradiction between lines 3-5 and lines 14-15 of Claim 9. In particular, "a test extract" possessing "the or each property required for the standard", does not agree with "the totality of the compounds in the plant material".



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : G01N 33/15, 24/08, G01R 33/46	A1	(11) International Publication Number: WO 00/47992 (43) International Publication Date: 17 August 2000 (17.08.00)																	
(21) International Application Number: PCT/GB00/00428 (22) International Filing Date: 10 February 2000 (10.02.00) (30) Priority Data: <table border="0"> <tr> <td>9903011.6</td> <td>10 February 1999 (10.02.99)</td> <td>GB</td> </tr> <tr> <td>60/120,591</td> <td>18 February 1999 (18.02.99)</td> <td>US</td> </tr> <tr> <td>9919573.7</td> <td>18 August 1999 (18.08.99)</td> <td>GB</td> </tr> <tr> <td>60/149,468</td> <td>19 August 1999 (19.08.99)</td> <td>US</td> </tr> <tr> <td>9928541.3</td> <td>2 December 1999 (02.12.99)</td> <td>GB</td> </tr> <tr> <td>60/168,382</td> <td>2 December 1999 (02.12.99)</td> <td>US</td> </tr> </table> (71) Applicant (for all designated States except US): OXFORD NATURAL PRODUCTS PLC [GB/GB]; No. 1 St. Giles, Oxford OX1 3JS (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): HYLANDS, Peter, John [GB/GB]; No. 1 St. Giles, Oxford OX1 3JS (GB). NICHOLSON, Jeremy, Kirk [GB/GB]; Imperial College of Science, Technology & Medicine, Alexander Fleming Building, Exhibition Road, London SW7 2AZ (GB). HOLMES, Elaine, Claire [GB/GB]; Imperial College of Science, Technology & Medicine, Alexander Fleming Building, Exhibition Road, London SW7 2AZ (GB). DUNN, Michael,	9903011.6	10 February 1999 (10.02.99)	GB	60/120,591	18 February 1999 (18.02.99)	US	9919573.7	18 August 1999 (18.08.99)	GB	60/149,468	19 August 1999 (19.08.99)	US	9928541.3	2 December 1999 (02.12.99)	GB	60/168,382	2 December 1999 (02.12.99)	US	John [GB/GB]; Coveham House, Downside Bridge Road, Cobham, Surrey KT11 3EP (GB). (74) Agents: KEEN, Celia, Mary et al.; J.A. Kemp & Co., 14 South Square, Gray's Inn, London WC1R 5LX (GB). (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
9903011.6	10 February 1999 (10.02.99)	GB																	
60/120,591	18 February 1999 (18.02.99)	US																	
9919573.7	18 August 1999 (18.08.99)	GB																	
60/149,468	19 August 1999 (19.08.99)	US																	
9928541.3	2 December 1999 (02.12.99)	GB																	
60/168,382	2 December 1999 (02.12.99)	US																	
(54) Title: PROCESS FOR QUALITY CONTROL AND STANDARDISATION OF MEDICINAL PLANT PRODUCTS																			
(57) Abstract																			
<p>A process for establishing a standard specification for a medicinal plant material comprises: (i) preparing a test solution or test extract of a sample of the medicinal plant material which is known to possess the or each property required for the standard; (ii) submitting the said solution or extract to two or more analytical methods including (a) a combination of NMR spectroscopy and a computer-based pattern recognition technique, and (b) one or more biological profiling techniques; (iii) obtaining results from the analytical methods used in step (ii); and (iv) establishing a standard specification for the said plant material on the basis of the results obtained in step (iii). Candidate samples of the medicinal plant material may subsequently be tested for compliance with the standard. They can be accepted or rejected depending on whether they give analytical results which fall within or outside either part or all of the specification established in step (iv). This approach to standardisation and quality control is particularly applicable to mixtures of medicinal plant materials.</p>																			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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INTERNATIONAL COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference N.75820B CMK	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 00428	International filing date (day/month/year) 10/02/2000	(Earliest) Priority Date (day/month/year) 10/02/1999
Applicant OXFORD NATURAL PRODUCTS PLC et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. **Certain claims were found unsearchable** (See Box I).

3. **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/00428

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 G01N33/15 G01N24/08 G01R33/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N G01R

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 18911 A (CONSEIL INTERPROFESSIONNEL DU ;VERCAUTEREN JOSEPH (FR); FORVEILLE) 20 June 1996 (1996-06-20)	10, 16
Y	page 1, line 7 -page 10, line 20	1, 4-6, 9
A	page 16, line 22 -page 18, line 21; claims 1, 2, 8-14; figure 6	2, 3, 7, 8, 11-15
Y	COOKE R J: "Gel electrophoresis for the identification of plant varieties" JOURNAL OF CHROMATOGRAPHY A, NL, ELSEVIER SCIENCE, vol. 698, no. 1, 28 April 1995 (1995-04-28), pages 281-299, XP004022963 ISSN: 0021-9673	1, 4-6, 9
A	the whole document	2, 3, 7, 8

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

16 June 2000

Date of mailing of the international search report

20/07/2000

Name and mailing address of the ISA

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Authorized officer

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/00428

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>KOWALSKI B R ET AL: "PATTERN RECOGNITION. A POWERFUL APPROACH TO INTERPRETING CHEMICAL DATA" JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, US, AMERICAN CHEMICAL SOCIETY, WASHINGTON, DC, vol. 94, no. 16, 9 August 1972 (1972-08-09), pages 5632-5639, XP000198394 ISSN: 0002-7863 cited in the application the whole document</p> <p style="text-align: center;">---</p>	1
A	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US PREV199799476639, 1997 PERRY, NIGEL B., ET AL.: "Alkamide levels in Echinacea purpurea: a rapid analytical method revealing differences among roots, rhizomes, stems, leaves and flowers." XP002140408 abstract</p> <p style="text-align: center;">---</p>	1
A	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US PREV199800038614, 1998 BARAKAT, HEBA H., ET AL.: "Polyphenolic metabolites of Epilobium hirsutum" XP002140409 abstract</p> <p style="text-align: center;">-----</p>	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/00428

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9618911 A	20-06-1996	FR 2732112 A	27-09-1996
		AU 4350396 A	03-07-1996
		ZA 9510722 A	02-07-1996
